

## **II. REMARKS**

Claims 1 to 81 are pending in the subject application. As a response to the requirement for restriction, claims 1 to 17 and 68 to 81 have been withdrawn from consideration. Claims 18 to 67 were examined in the first Office Action. By this Amendment and Response, claims 18 to 20, 22, 24, 26-33, 35, 38, 39, 42 to 44, 46 to 48, 52, 56, and 58 to 60 have been amended without prejudice or disclaimer. Support for the amendments to the claims is found throughout the specification as filed. Claims 30 and 45 have been canceled in this paper. The amendments to the claims and the cancellation of claims 30 and 45 are made without prejudice or disclaimer and are not intended to be a dedication to the public of the subject matter of the claims or the equivalents thereof. Applicants expressly reserve the right to continue prosecution of the claims as originally presented in a later filed application.

An issue of new matter is not raised by these amendments and entry thereof is respectfully requested.

In view of the preceding amendments and the remarks that follow, reconsideration and withdrawal of the objections to and rejections of the claims is respectfully requested.

### **Objection to the Title**

The Office alleged that the title of the invention is not descriptive of the elected invention and therefore requested a new title. In response to the Office's request, the title has been amended to "A Method, System, and Computer Program Product for Identifying Drug Targets and Enzymes," as suggested by the Office. Reconsideration and withdrawal of the objection is respectfully requested.

### **Objection to the Specification**

The disclosure was objected to on the ground it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 25, lines 11-12 and pages 78-82. The specification has been amended as requested by the Office and therefore, removal of the objection is respectfully requested.

## **Objections to the Claims**

Claims 18, 19, 33, 35, 44, 47, 52, and 60 were objected to because of the following minor informalities:

"Claim 18, lines 2, 6, and 11 list 'a.', 'b.', and 'c.' which is an improper use of periods.

Claim 35, lines 2, 5, 8, 13 and 19 list 'a.', 'b.', 'c.', 'd.', and 'e.' which is an improper use of periods.

Claim 52, lines 3, 6, 11, and 15 list 'a.', 'b.', 'c.', and 'd.' which is an improper use of periods.

Claim 60, lines 4, 7, and 11 list 'a.', 'b.', and 'c.' which is an improper use of periods.

The Office requested deletion of these periods.

Claim 18, line 8, recites the word 'comprises' which should be in plural form because the word "sets" (line 7) is plural.

Claim 18, line 9, recites the phrase 'that *is* different *that*' which does not make grammatical sense with the rest of section (b) of claim 18. The word 'is' should be in plural form since the word 'classes' (line 9) is in plural form. The phrase would also be grammatically correct if the second 'that' of line 9 was changed to 'than'.

Claim 19, line 3, recites the word 'organism' which should be in the plural form.

Claim 33, line 2, recites the word 'comprises' which should be in the plural form.

Claim 44, line 2, recites the phrase 'on a one' which does not make grammatical sense. Correction is suggested by deleting the word 'a'.

Claim 47, line 2, recites the term 'comprises' which should be in the plural form.

Claim 52, line 8, recites the term 'comprises' which should be in the plural form.

Claim 52, line 8, recites the phrase 'one or logic' which does not make grammatical sense and appears to be missing a word.

Claim 52 is objected to because it does not fall in the statutory class of methods and yet it contains method steps which is inappropriate."

Appropriate corrections were requested by the Office.

Without conceding the correctness of the Office's position and to expedite examination of the application, the offending claims have been amended to remove the grounds for objection.

In view of these amendments, reconsideration and withdrawal of the objections is respectfully requested.

### **35 U.S.C. § 101**

Claims 18-51 stand rejected under 35 U.S.C. § 101 on the ground that the claims are allegedly directed to non-statutory subject matter. The Office stated that as written, the claims appear to lack any physical result performed outside of a computer, for example, claims 25, 27, 40, and 42 mention outputting and displaying a list of enzymes, but the claims do not suggest that this is necessarily taking place outside of a computer. The Office also stated that as written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

Without conceding the correctness of the Office's position and to expedite examination of the application, the claims have been amended to remove the grounds for rejection. In view of these amendments, reconsideration and withdrawal of the objections is respectfully requested.

### **35 U.S.C. § 112, First Paragraph**

Claims 18-51 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly corrected, to make and/or use the claimed invention.

The Office stated that:

"method claims 18 and 35 create output in step (c) (in both claims) and step (e) (in claim 35) wherein the target enzymes are found in bacteria but not in the one or more other classes organisms used in the comparisons. The target enzymes of these outputs are then called 'drug targets' at the end of these steps. Calling these enzymes drug targets' seems like an overly bold statement to make based simply on the comparisons that take place in these methods. In actuality, these enzymes only seem to be *putative* drug targets. It would not be until after a large amount of additional experimentation has taken place, including synthesis of enzymes and drugs as well as testing the enzymes against various drugs, before one of skill in the art would consider them to be properly classified as drug targets. Therefore,

claims 18 and 35 and the dependent claims therefrom are rejected due to the lack of enablement.”

Without conceding the correctness of the Office’s position, and merely to advance examination of the claims, the allegedly offending claims have been amended as suggested by the Office. In view of these amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

### **35 U.S.C. § 112, Second Paragraph**

Claims 18-67 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the inventions.

The Office alleged that claims 24, 34, 39, 51, 52, 57, and 65 are vague and indefinite due to the unclarity of citing an abbreviation, such as FAST, iECTA, ECTA, TCP/IP, and IPX, and thus, correction is suggested. Claims 53-56 and 58-59 also stand rejected due to their dependency from claim 52.

Applicants respectfully traverse the grounds for rejection for the reasons which follow. The Federal Circuit has held that claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made in order to determine if a claim satisfies the requirements of 35 U.S.C. § 112, second paragraph. See, e.g., *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure). As noted in *S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 59 U.S.P.Q.2d 1745 (Fed. Cir. 2001):

"The purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification."

*Id.* at 1369.

Thus, Applicants maintain that the claims, read in light of the disclosure, satisfy the requirements of 35 U.S.C. § 112, second paragraph. The fact that some of the claim terms are acronyms or abbreviations is not a basis for *ipso facto* rejection of the claims. In support of their position, Applicants direct the Examiner's attention to U.S. Pat. Nos. 6,303,297B1 and 6,553,317B1 which were cited by the Office in the outstanding Office Action. Both patents utilize the abbreviation "cDNA" in the claims.

Thus, Applicants maintain that the Office has not presented a *prima facie* basis for the above-noted rejection. Accordingly, removal of the grounds for rejection is respectfully requested.

The Office also stated that:

"[c]laims 18 (line 3-4), 35 (lines 3-4), 52 (lines 4-5) recite the phrase "first enzymes" which is vague and indefinite. It is unclear in what reference the enzymes are considered to be 'first'. For example, the enzymes could be the first enzymes produced by an organism or the first enzymes recognized by an organism or countless other scenarios. Clarification of 'first enzymes' is requested. Claims 19-34, 36-51, and 53-59 are also rejected due to their direct or indirect dependency from claims 18, 35, and 52.

Claim 18, line 9, recites the phrase 'that is different than [sic]' which is vague and indefinite. It is unclear if this difference is referring to a difference between the expressed enzymes from the enzymes of the target organism or to a difference between the classes of organisms and the target organism. Clarification of this issue via clearer claim wording is requested. Claims 19-34 are also rejected due to their direct or indirect dependency from claim 18.

Applicants respectfully traverse. As noted above, claims are to be read in light of the specification when evaluated for definiteness. Applicants' specification (e.g., see pages 78 to 94)

and the figures (e.g., Figure 2C) adequately define the term “first enzymes”. For this reason, the rejection is improper and therefore should be removed.

The Office further noted that:

“Claims 20, 24, and 39 are vague and indefinite due to the inclusion of embodiments beyond the elected invention. Correction is suggested by stating only the elected invention, such as ‘bacteria’ and ‘FAST algorithm.’”

The claims have been amended to overcome this ground for rejection.

The Office also alleged that:

“Claim 19, line 1, recites the phrase ‘the enzymes’ which is rejected due to lack of clear antecedent basis. It is unclear to which group of enzymes in claim 18 that ‘the enzymes’ is supposed to be referring. Clarification with proper antecedent basis for this phrase is requested.

Claim 21, line 1, recites the phrase ‘the organism’ which is rejected due to the lack of clear antecedent basis. It is unclear to which ‘organism’ in claim 18 that ‘the organism’ is supposed to be referring. As currently written, ‘the organism’ could be referring to the target organism (claim 18, line 4) or one of the organisms that is different than the target organism (claim 18, lines 9-10). Clarification with proper antecedent basis for this phrase is requested.

Claim 22, line 1, recites the phrase ‘the animal’ which is rejected due to the lack of antecedent basis. Claim 22 is dependent from claim 18; however, claim 18 does not include the term ‘animal’ in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase ‘the animal’ is requested.

Claim 24, line 1, recites the phrase ‘the alignment search algorithm’ which is rejected due to the lack of antecedent basis. Claim 24 is dependent from claim 18; however, claim 18 does not include the phrase ‘alignment search algorithm’ in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase ‘the alignment search algorithm’ is requested.

Claims 19, 21, 22 and 24 have been amended herein to remove the grounds for rejection.

Claim 27, lines 1-4, recites the phrases ‘the metabolic enzymes’ and ‘the non-metabolic enzymes’ which are rejected due to the lack of clear antecedent basis. It is unclear if ‘the metabolic enzymes’ in claim 27 (lines 2 and 3) are referring to the ‘metabolic enzymes’ on line 2 of claim 26 or of the ‘metabolic target enzymes’ on lines 4 and 5 of claim 26. It is also not entirely clear if ‘the non-metabolic enzyme’ in claim 27 (lines 2-4) are referring to the ‘non-metabolic

*target enzymes*' of claim 26 (lines 6-7). Clarification of this lack of clear antecedent bases for these phrases is requested.

Claim 28, line 1, recites the phrase 'steps utilize a network' which is vague and indefinite. It is unclear how method steps can utilize anything. Instead, it seems more logical that method steps *can be performed* on a network. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 29, line 1, recites the phrase 'the network' which is rejected due to the lack of antecedent basis. Claim 29 is dependent from claim 18; however, claim 18 does not include the term 'network' in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase 'the network' is requested.

Claim 30, lines 1-2, recites the phrase 'step utilizes a user's computer' which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more logical that a method step *can be performed* on a user's computer. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 31, line 2, recites the phrase 'relating to' which is vague and indefinite. It is unclear in what way the numbers are relating to the first set of enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 31, lines 2-3, recites the phrase 'the first set of enzymes' which is rejected due to the lack of clear antecedent basis. The first enzymes mentioned as being associated with a target organism in claim 18, lines 3-4, were not previously defined as being in a set of enzymes, but rather just first enzymes. Clarification with proper antecedent basis for the phrase 'the first set of enzymes' is requested.

Claim 32, line 2, recites the phrase 'relating to' which is vague and indefinite. It is unclear in what way the numbers are relating to the one or more expressed enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 35, line 2, recites the phrase 'the first data structure' which is rejected due to the lack of antecedent basis for this phrase. Amending the word 'the' to 'a' would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, lines 2-3, recites the phrase 'the first set of information' which is rejected due to the lack of antecedent basis for this phrase. Amending the word 'the' to 'a' would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 7, recites the phrase 'second enzymes' which is vague and indefinite. It is unclear with what reference the enzymes are considered to be

second. For example, they could be the second enzymes to appear in timed response or countless other scenarios. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 7, recites the phrase ‘first class of organism’ which is vague and indefinite. It is unclear if this type of organism is intended to be considered the same as the organism mentioned in line 4 or what constitutes an organism to be ‘first class.’ Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 9, recites the phrase ‘the first output’ which is rejected due to the lack of antecedent basis for this phrase. Amending the word ‘the’ to ‘a’ would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 14, recites the phrase ‘relating to’ which is vague and indefinite. It is unclear in what way the information is relating to the third expressed enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 14, recites the phrase ‘third expressed enzymes’ which is vague and indefinite. It is unclear what is meant by these enzymes being third. It is unclear if these enzymes are only expressed by a third of their normal expression or countless other scenarios. Clarification of the metes and bounds of this phrase is requested via clearer claim wording. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, lines 15 and 18, recites the phrase ‘second class of organisms’ which is vague and indefinite. It is unclear if this type of organism is the same or different from the target organism. Clarification of the metes and bounds of this phrase is requested via clearer claim wording. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 22, recites the phrase ‘the target enzymes’ which is rejected due to the lack of clear antecedent basis for this phrase. The claim does mention enzymes as well as target organisms, but this does not provide clear antecedent basis for ‘the target enzymes’. It is unclear if the target enzymes are supposed to be enzymes from the target organism or if the enzymes are considered targeted for some other reason. Clarification with proper antecedent basis for the phrase ‘the target enzymes’ is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 36, lines 1-2, recites the phrase ‘repeating steps (d)-(e)  $n$  times, wherein there are  $n$  data structures’ which is vague and indefinite. It is unclear which data

structures should be compared to which other data structures in this scenario. For example, if there are four data structures, then are there fourth expressed enzymes? Are these enzymes associated with the same second class of organism or a third class of organism? Are they different from a first class of organism and/or a second class of organism? Are the enzymes expressed at elevated levels in the new class of organisms compared to any other class of organism or the next lower class? Since countless plausible scenarios exist, clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 38, lines 1-2, recites the phrase ‘step utilizes an alignment search algorithm’ which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more logical that a method step *can be performed* by an alignment search algorithm. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 42, lines 2-4, recites the phrases ‘the metabolic enzymes’ and ‘the non-metabolic enzymes’ which are rejected due to the lack of clear antecedent bases for these phrases. It is unclear if the ‘the metabolic enzymes’ of claim 42 are referring to the metabolic enzymes of claim 41, line 2, or to the metabolic target enzymes of claim 41, line 4. It is also not entirely clear if ‘the non-metabolic enzyme’ in claim 42 (lines 2-4) are referring to the ‘non-metabolic *target* enzymes’ of claim 41 (lines 6-7). Clarification of this lack of clear antecedent bases for these phrases is requested.

Claim 43, line 1, recites the phrase ‘steps utilize a network’ which is vague and indefinite. It is unclear how method steps can utilize anything. Instead, it seems more logical that method steps *can be performed* on a network. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 44, lines 1-2, recites the phrases ‘the network’ and ‘the *n* data structures’ which are rejected due to the lack of antecedent bases for these phrases. Claim 44 is dependent from claim 35; however, claim 35 does not include the terms ‘network’ or ‘*n* data structures’ in order to have proper antecedent basis. Clarification with proper antecedent basis for phrases ‘the network’ and ‘the *n* data structures’ is requested.

Claim 45, lines 1-2, recites the phrase ‘step utilizes a user’s computer’ which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more logical that a method step *can be performed* on a user’s computer. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 46, line 2, recites the phrase ‘relating to’ which is vague and indefinite. It is unclear in what way the numbers are relating to the first set of enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claims 47 and 48 (line 1 of each) recite the phrases ‘the *n* data structures in the group’ and ‘the *n* data structures’ which are rejected due to the lack of antecedent bases for these phrases. Claims 47 and 48 are dependent from claim 35; however, claim 35 does not include the phrases ‘*n* data structures in the group’ or ‘*n* data structures’ in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrases ‘the *n* data structures in the group’ and ‘the *n* data structures’ is requested.

Claim 49, line 1, recites the phrase ‘the class of organism’ which is rejected due to the lack of clear antecedent basis. It is unclear to which class of organism in claim 35 that ‘the class of organism’ is supposed to be referring. As currently written, ‘the class of organism’ could be referring to the first class of organism (claim 35, line 7) or the second class of organism (claim 35, line 18). Clarification with proper antecedent basis for this phrase is requested. Claim 50 is also rejected due to its dependency from claim 49.

Claim 52, line 9, recites the phrase ‘a first data structure to obtain a first set of information’ which is rejected due to its unclarity regarding antecedence. It is unclear if this ‘a first data structure to obtain a first set of information’ is the referring to the ‘a first data structure to obtain a first set of information’ on lines 3-4 of this claim. If so, then the words ‘a’ should be changed to ‘the’ to provide proper antecedent basis for this phrase. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claims 52 (lines 9 and 12), 58 (line 1), 59 (line 2) recite the phrase ‘relating to’ which is vague and indefinite. It is unclear in what way the information is relating to the enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claim 52, line 10, recites the phrase ‘a target organism’ which is rejected due to its unclarity regarding antecedence. It is unclear if this ‘a target organism’ is the referring to the ‘a target organism’ on line 5 of this claim. If so, then the word ‘a’ should be changed to ‘the’ to provide proper antecedent basis for this phrase. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claim 56, line 2, recites the phrase ‘the second data structure’ which is rejected due to the lack of antecedent basis for this phrase. Claim 56 depends from claim 52 which does not mention a second data structure. Clarification of the proper antecedent basis for the phrase ‘the second data structure’ is requested. Claim 57 is also rejected due to its dependency from claim 56.

Claims 60 (lines 5 and 8), 66 (line 2), and 67 (line 2) recite the phrase ‘relating to’ which is vague and indefinite. It is unclear in what way the information is relating to the enzymes. Clarification of the metes and bounds of this phrase via clearer

claim wording is requested. Claims 6 1-65 are also rejected due to their direct or indirect dependency from claim 60.

Claim 64, lines 2-3, recites the phrase ‘the second data structure’ which is rejected due to the lack of antecedent basis for this phrase. Claim 64 depends from claim 60 which does not mention a second data structure. Clarification of the proper antecedent basis for the phrase ‘the second data structure’ is requested. Claim 65 is also rejected due to its dependency from claim 64.”

Applicants respectfully traverse. Without conceding the correctness of the Office’s position and to advance examination the claims have been amended herein without prejudice or disclaimer. In view of these amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

### **35 U.S.C. § 102**

Claims 18-25, 28-30, 33, 35-36, 38-40, 43-45 and 48-50 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Lincoln (P/N 6,553,317 B1).

Briefly, the Office argued that Lincoln et al. discloses systems and methods for identifying genetic information and materials that may be used for further research and drug development (drug targets) (col. 1, lines 25-30 and col. 4, lines 10-14). Lincoln et al. is alleged to disclose using a computer system with a relational database containing polynucleotide sequences (col. 2, lines 28-34) assessing related information by way of a user entering a query relating to one or more sequences (data structures), determining matches between the query and the information and displaying the results (col. 2, lines 38-50). The Office noted that in Figure 1A, Lincoln et al. allegedly discloses comparing sequences against internal databases (10) and public gene, protein, and pattern databases (16), noting matches (18), as well as unique clones (20), known as the *first output* in instant claim 1), recording the results of matches and unique clones in tables (22) (a third data structure), and placing the results gene expression and sequence relational databases (24). Lincoln et al. is argued to disclose investigating biomolecular sequences from various sources, including microbial, plant, human, primate, rodent, amphibian, and insect sequences (col. 4, lines 3-7).

The Office stated that therefore, Lincoln et al. illustrates if microbial sequences were queried, then the unique clones ((20) of Figure 1A and col. 5, lines 41-64) would include only sequences from the microbe, as stated in instant claim 19. Lincoln et al. also is alleged to disclose noting variations in the relative frequency of Expressed Sequence Tags (ESTs) to detect the differential expression of the corresponding genes (col. 1, lines 46-61). The Office further noted that Lincoln et al. discloses categorizing master clusters (318) to classify hierarchies for enzyme function and protein function which allows users to search all, sequences in the gene expression database that are associated with a particular protein or enzyme function (col. 18, line 66 to col. 19, line 5) which suggests a third data structure to organize enzymes.

Thus, the Office concluded, Lincoln et al. anticipates claims 18-25, 28-30, 33, 35-36, 38-40, 43-45, and 48-50.

Applicants respectfully traverse. A reference is anticipating only if provides each and every element of the rejected claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.

Applicants traverse on the ground that the cited patent fails to cite each and every element of the rejected claims.

Applicants' claims currently under examination relate to systems and methods for identifying putative drug targets for which pharmaceuticals and the like can be developed. The methods generally require the steps of:

- "(a) searching a first data structure to obtain a first set of information, wherein the first set of information comprises first enzymes associated with a target organism or in a pathogen-infected cell;
- (b) searching one or more data structures to obtain one or more sets of information, wherein the one or more sets of information comprise one or more expressed enzymes associated with one or more respective classes of organisms that are different from the target organism; and
- (c) comparing the first set of information to the one or more sets of information with the computer processing means to create a first output, wherein the first output comprises target enzymes in the first

set of information that are not present in the one or more sets of information, and wherein the target enzymes are putative drug targets.”

In contrast, U.S. Patent No. 6,553,317 B1 “relates generally to relational databases for storing and retrieving biological information.” Col. 1, l. 25-26, of the patent (emphasis added). The patent teaches how to build a database of cDNA sequence information obtained from partial coding sequences, e.g., an Expressed Sequence Tag (“EST”) for the purpose of compiling the open reading frame from a number of overlapping sequences.

Column 7, lines 44-53 notes that:

“Before entering the functional analysis block (which performs step 16), new sequences are compared against existing clone sequences stored in an internal database (e.g., an Incyte Pharmaceuticals, Inc. LifeSeq® relational database) at step 12; this step is the basis for the cluster assignments. Preferred clustering techniques will be discussed in detail below. For now, it should be recognized that the clustering process looks for overlap between terminal sequences of clones (1) to construct longer sequences (clusters) composed of the individual overlapping clones, and (2) to classify new clones as belonging to a known sequence already provided in the internal database. As the EST clones described herein are rather short (e.g., 50-300 base pairs), they do not represent full length mRNA. Therefore, their information content can be increased when they are clustered.”

Thus, the “first set of information” of the cited patent relates to “partial” sequence information isolated from a biological sample. The first set of information does not comprise first enzymes associated with a target organism or in a pathogen-infected cell as required by Applicants’ claims. In addition the second set of information against which the sequences of the partial clones are compared are not necessarily from a different class of organism.

Accordingly, the elements of the rejected claims are not disclosed by U.S. Patent No. 6,553,317 B1. The rejection is in error and therefore should be removed.

### **35 U.S.C. § 103**

Claims 18-25, 28-40, 43-53, 55-61, and 63-67 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Lincoln et al. (U.S. Patent No. 6,553,317) in view of Shepard (U.S. Patent No. 6,245,750) and Lincoln et al. (U.S. Pat. No. 6,303,297).

Lincoln et al. ('317) allegedly describes the limitations of claims 18-25, 28-30, 33, 35-36, 38-40, 43-45, and 48-50, as discussed above (see 102(a) rejection). However, the Office acknowledged that Lincoln et al. ('317) does not describe the use of Enzyme Commission numbers, or designing Enzyme Catalyzed Therapeutic Activation (ECTA) and iECTA compounds.

Lincoln et al. ('297) also allegedly describes using a relational database that stores an expression database with sequence data and which comprises a plurality of tables organized into categories (col. 3, lines 38-44) and storing Genbank location and international EC numbers in the protein table (720) which corresponds to sequences (col. 20, lines 21-29). Lincoln et al. also is alleged to describe protein function analysis consisting of numerous divisions of analysis including enzyme hierarchy as assigned with the Enzyme Commission (EC) list and based on level of functioning (expression) (col. 23, lines 22-35).

The Office stated that "Shepard describes identifying potential therapeutic agents that are enzyme catalyzed therapeutic agents (ECTA) by contacting a target with a candidate therapeutic agent or prodrug which is selective for a target enzyme (col. 5, lines 19-34). Shepard describe in one embodiment that a target enzyme is an endogenous, intracellular enzyme (col. 5, lines 24-26). Shepard describe in another embodiment that a target enzyme is an expression product of an infectious agent in the cell (col. 5, lines 32-35) which seems to fit the definition of iECTA of the instant invention as described on page 7, lines 1-5, of the specification. Shepard describe the field of drug discovery and designing prodrugs (col. 1, lines 15-19)."

The Office argued that Lincoln et al. ('317) state today's researchers require advanced quantitative analyses, database comparisons, and computational algorithms to explore the relationships between sequence and phenotype via computers (col. 1, lines 38-45) and that sophisticated computer database systems have been developed to make EST information manipulation easy to perform and understand (col. 1, lines 62-63). The Office remarked that Lincoln et al. ('317) states that while relational database systems provide great power, this area of technology is still in its infancy and requires further improvements to help accelerate biological research for numerous applications (col. 2, lines 6-11). The Office concluded that therefore, it

would have been obvious to a person of ordinary skill in the art at the time the invention was made to add sequence information with biological annotations provide information in relational databases for a user provides access to this information, as stated by Lincoln et al. ('317), so that further application in research and therapeutic pharmaceutical development could occur, (col. 2, lines 14-27). The Office further argued that a person of ordinary skill in the art would have been motivated to add Enzyme Commission numbers, as stated by Lincoln et al. ('297) in order to further classify and efficiently organize data (col. 23, lines 22-35) and then proceed with designing ECTA and iECTA compounds, as stated by Shepard, in order to accelerate biological research in the drug development area, as stated by Lincoln et al. ('317) (col. 23-25).

Applicants respectfully traverse. Applicants incorporate herein by reference the grounds for traversal of the rejection over the teachings of U.S. Patent No. 6,553,317 B1. Briefly, the '317 patent does not disclose a method to identify putative drug targets using sets of information relating to enzymes associated with a target organism or in a pathogen-infected cell, as alleged by the Office. The patent teaches how to build and use computer systems to compile and identify sequences encoding the open reading frames of expressed genes. Small partial sequence information is collected and organized and subsequently compared to other known sequence information, public or private. The Office has not provided reasoned statements how the secondary references show up the deficiencies present in the primary reference (the '317 patent). Accordingly, the Office has failed to present a *prima facie* case of obviousness. Accordingly, reconsideration and withdrawal of the grounds for rejection under 35 U.S.C. § 103, is respectfully requested.

### III. CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to

**Deposit Account No. 50-2518**, billing reference number **7008392001**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: April 15, 2004

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